



### The COVID-19 Vaccine: Everything You Need to Know

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President and Chief Executive Officer

Dan Roth, M.D.

Executive Vice President and Chief Clinical Officer

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Senior Vice President and Chief Medical Officer

### Welcome to the System Office Town Hall

- Thank you for joining!
- All lines are muted
- To ask a question, type it in the Q&A



- Questions not yet answered will be published and answered during or after the event
- This event is being recorded; the link will be shared following the meeting
- Please display your name in support of mutual transparency



### **Presenters**



Michael Slubowski
President and Chief
Executive Officer



Syed Hussain, M.D.
Senior Vice President and
Chief Clinical Officer,
Trinity Health Of New
England



**Dan Roth, M.D.** Executive Vice President and Chief Clinical Officer



Tammy Lundstrom, M.D., J.D.
Senior Vice President
and Chief Medical Officer



### Reflection

Syed Hussain, M.D.

Senior Vice President and Chief Clinical Officer Trinity Health Of New England



#### "My answer now would be absolutely get it, you don't want to be where I've been."



Robby Walker of Florida was hesitant to receive the COVID-19 vaccine. Then in July, he came down with COVID-19. He was on a ventilator but still unable to keep his blood oxygenated on his own. He needed a specialized type of ventilator to have a chance to survive. Robby's wife went on the news begging for help to get him ECMO treatment as all machines in their home state were being used.

Trinity Health of New England Chief of Cardiothoracic Surgery Robert Gallagher, M.D. heard her plea and Robby was transferred to St. Francis Hospital in Connecticut for the life-saving treatment for 22 days.

Robby returned home in mid-October and received his second vaccine dose shortly after. Not only has his experience changed his perspective but also that of those around him. His story has inspired many friends and family members to get vaccinated.

"My answer now would be absolutely get it, you don't want to be where I've been."





### One of the Largest Catholic Health Care Systems in the Nation

\$20.2B

**25** 

States

1.4M

Attributed Lives

In Revenue

\$1.2B

Community Benefit Ministry

115K Colleagues 6.8K

Employed Physicians & Clinicians

25.8K

Affiliated Physicians

88
Hospitals\*

17

Clinically Integrated Networks

131

Continuing
Care Locations\*

25

PACE Center Locations\*

125

Urgent Care Locations\*

FY21 data unless noted

Exclusions: Mercy Chicago Hospital transitioned to Insight Chicago (June 2021); Mercy Philadelphia Hospital transitioned to Penn Medicine (March 2021)

\*Owned. managed or in JOAs or JVs

v: 10.25.21



### Our Mission

We, Trinity Health, serve together in the spirit of the Gospel as a compassionate and transforming healing presence within our communities.

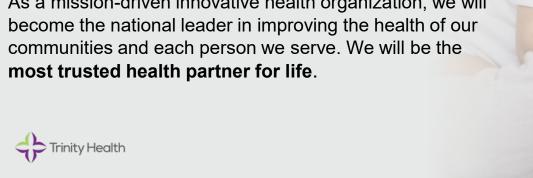
### Our Core Values

Commitment to Those Who are Poor Reverence

Safety | Justice Stewardship Integrity

### Our Vision

As a mission-driven innovative health organization, we will become the national leader in improving the health of our most trusted health partner for life.





### **Trinity Health**

has administered more than

1.15M

### **COVID-19 vaccinations**

from the 1.2M doses received.<sup>1,2</sup>

As of Oct. 4, 2021



<sup>1</sup>Source: Self-reported COVID-19 vaccination statistics in REDCap. The number of vaccinated persons refers to any individuals that receive the vaccine at a Trinity Health vaccination site including Trinity Health colleagues.

<sup>2</sup>Source: https://covid.cdc.gov/covid-data-tracker/#vaccinations



# For safety, more organizations are requiring employees to be vaccinated

- Health care facilities receiving Medicare or Medicaid funds must have workers vaccinated
- Health care is leading the way in vaccinations

## More than 99% of Trinity Health Colleagues Took Action to Meet Vaccination Requirement

- Trinity Health was the first national health system to announce a vaccination requirement for colleagues, affiliated physicians, students and vendors
- Our clinicians and colleagues are living our values and protecting our patients and communities







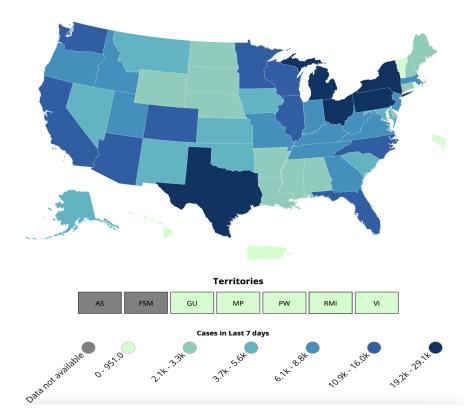
## Variants or mutations to the COVID-19 virus are driving cases up

- Viruses mutate over time, some more easily than others
- The Delta variant is currently the most common variant
- The mutations have made some of these strains more transmissible, but the vaccines still work – and are highly effective against hospitalization and severe illness
- Booster doses are now available in certain populations to further decrease risk of infection in those whose immunity may have waned over time
- A study done by the CDC demonstrated risk of reinfection with COVID for those who had suffered COVID illness was 2.3 times less likely if they received vaccination after they had recovered from COVID illness



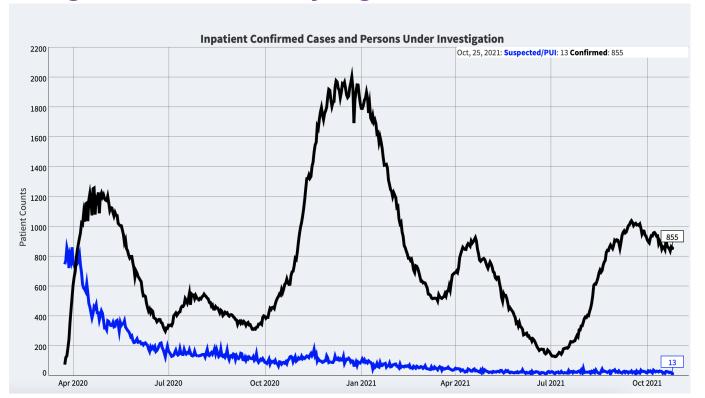
Cases over the last 7 days are declining, however, we continue to have about 80,000 new cases per day in the





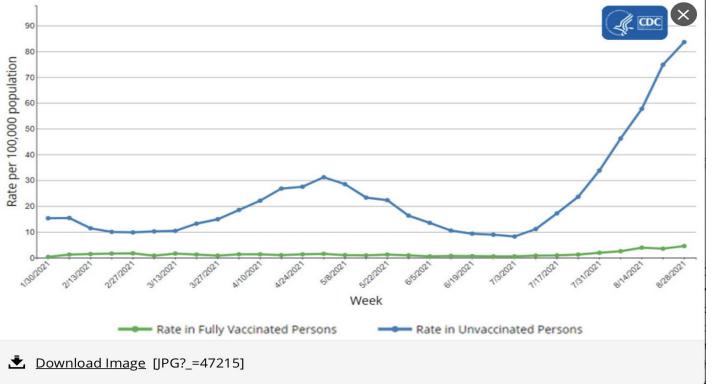


### Consistent with national figures, hospitalizations in this 5<sup>th</sup> surge are declining, but remain at very high levels





While hospitalizations have increased slightly for fully vaccinated, the overwhelming majority are in unvaccinated





## A majority (67.2%) of those in the US currently eligible for vaccination are fully immunized

- 57.4% of total U.S. population now fully vaccinated
  - Ages 12+ 67.2%
  - Ages 18+ 68.9%
  - Ages 65+ 84.7%
- More than 413.6 million doses administered in the U.S.
- More than 12.9 million booster doses administered
- The vaccine is safe
- It is effective against the Delta variant and other variants



(Data as of 10/25/21)



## Pfizer COVID-19 Vaccine Receives Permanent FDA Approval

- Aug. 23: The FDA granted permanent biologic license approval of the Pfizer COVID-19 vaccine for people ages 16 and older
- The vaccine passed numerous, required safety checks including study of all reported side effects and any adverse reactions.
- Safety data showed the vaccine is safe and effective





## CDC recommends 3<sup>rd</sup> dose for mRNA vaccines for moderately to severely immunocompromised (weakened immune systems) under EUA



 A single dose offers some protection



 The second dose significantly improves immune system's memory of how to fight the virus



- Scheduled for 28 days or more following Dose 2
- For those who received mRNA vaccines either mRNA vaccine could be used as a third dose
- Immunocompromised who initially received J&J they can get a dose of either J&J or mRNA 2 months or more after single dose J&J



## FDA and CDC have recommended booster dose for mRNA vaccinees 6 months after dose 2 for high risk



- Antibody levels decrease over time
- Delta variant more transmissible and more symptomatic illness seen in vaccines
- 6 months following second dose

#### Boosters are recommended for:

- 65 years of age or older
- 18-64 with conditions that put them at high risk of severe COVID illness
- 18-64 who are institutionalized or whose occupation puts them at risk of repeated exposure



## Conditions that cause high risk for severe disease

- Cancer
- Chronic liver disease
- Chronic kidney disease
- Chronic lung disease
- Dementia
- Diabetes (Type 1 or 2)
- Down syndrome
- Heart conditions, including high blood pressure
- HIV

- Immunocompromised
- Mental health conditions
- Overweight/obesity
- Pregnancy
- Sickle cell/thalassemia
- Smoking (even former)
- Solid organ/stem cell transplant
- Stroke/cerebrovascular disease
- Tuberculosis



## FDA/CDC have recommended booster dose for J&J vaccinees 2 months after single dose for everyone 18 and older who received J&J



- · Antibody levels decrease over time
- Delta variant more transmissible and more symptomatic illness seen in vaccines
- 2 months following second dose

Boosters are recommended for:

18 years of age or older



## The side effects and safety profile of booster doses is similar to primary vaccine series

- Most common side effects were sore arm, fatigue, headache, muscle aches and low grade fever
- No additional/new safety concerns were identified
  - Rare myocarditis after mRNA
  - Rare thrombosis with thrombocytopenia syndrome and Guillian-Barre syndrome after J&J



## CDC data on vaccination in early pregnancy shows no concerns

- Earlier studies showed no increase in spontaneous abortion, stillbirth or small for gestational age
- 2,500 pregnant women- no increased risk of miscarriage in those who received mRNA vaccine before 20 weeks gestation (13% vs. 11-16%)
- Currently there is no evidence linking vaccines to infertility
  - Over 4,800 women had a positive pregnancy test after getting vaccination
- Studies in 45 healthy men showed no significant changes in sperm counts or characteristics after vaccination





## Pregnant women at increased risk for poor outcomes with COVID-19

### **COVID-19 infection in pregnancy:**

- Increases the risk of preterm birth
- Increases the risk of baby being admitted to the Neonatal Intensive Care Unit (NICU)
- Increases the risk of stillbirth
- 97% of pregnant women hospitalized with COVID-19 are unvaccinated

### Pregnant women who are unvaccinated:

- Are 60% more likely to go into preterm labor
- Have a 70% increased risk of death from COVID-19 illness
- Three times as likely to be admitted to the ICU



Vaccinating children is safe and effective

 10.9 million children (46%) 12–17 years old (46%) are fully vaccinated\*

 More children are being hospitalized with COVID-19: 1,902 inpatients, comprising 2.4% of all hospitalizations in recent surge

 COVID-19 is currently the eighth leading cause of death in children

- Children experienced similar side effects as adults
- The Pfizer vaccine has received FDA EUA authorization as safe and effective in children ages 5-11, and CDC/ACIP meets November 2<sup>nd</sup>-3<sup>rd</sup> to develop criteria for use
- Children ages 5-11 still receive two shots 21 days apart, but at a reduced dose

(\*Data as of 10/06/21)



## Myocarditis after mRNA vaccination is rare and usually mild

- Cases are rare- about 13.4/million vaccinated overall
- Myocarditis (heart inflammation) is more common in those under age 30 and male
- Usually shows up 1-3 days after vaccination as shortness of breath or chest tightness and an occur after either dose
- Usually causes mild symptoms and treated as outpatients
- People who are infected with COVID-19 have 16-18 times higher risk for myocarditis than those without COVID
- The risk of myocarditis from COVID infection is 6-34 times higher than the risk in those who receive the vaccine (varies by age and sex)



### Treatments are available but vaccination remains the best way to prevent severe illness and death

- While we have treatments such as remdesivir and dexamethasone (steroid) to treat those hospitalized, about 1200 deaths still are occurring daily
- Monoclonal antibody treatments are available to try to prevent those who are infected and at high risk from becoming severely ill
- Monoclonal antibody treatments are available as prophylaxis to try to prevent those who are exposed from becoming ill
- A new oral medication is being reviewed by the FDA for potential treatment for mild-moderate disease in outpatients



### **Mythbusters**

- Being near someone who has been vaccinated can:
  - affect my menstrual cycle
  - cause me to have myocarditis
  - give me COVID-19
- Vaccination can cause people to become magnetized
- Vaccination causes infertility
- Vaccination causes COVID variants
- There are thousands of vaccine-related deaths



### Summary

- Vaccines are very effective against severe disease, hospitalization, and death
- Vaccine effectiveness against infection (symptomatic and asymptomatic) has decreased over time, especially with the Delta variant
- All pregnant women and those trying to become pregnant should be vaccinated to protect against severe disease
- Anticipating further waning immunity and the ongoing Delta surge, boosters are now being offered to all those who received J&J and highrisk populations who received mRNA vaccines
- FDA committee just recommended EUA for Pfizer vaccine in ages 5-11 (pending FDA EUA and CDC recommendations)
- While treatments are available, vaccination continues to be the best method to prevent severe illness and death



